JAN 2 6 2009

510(k) Summary for

Berichrom™ Heparin UF Calibrator

Berichrom™ Heparin UF Control 1

Berichrom™ Heparin UF Control 2

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807 92

The assigned 510(k) number is K083175

A Manufacturer's Name, Address, Contact Information, and Date of Preparation

1 Manufacturer

Siemens Healthcare Diagnostics Products GmbH

Emil-von-Behring Str 76

35041 Marburg, Germany

2 Contact Information

Siemens Healthcare Diagnostics Inc

500 GBC Drive

Newark, Delaware 19702

Attention Janet Fose, Regulatory Affairs Specialist

Telephone 302-631-8826, Fax 302-631-6299

3 Preparation Date October 27, 2008

B Name of Device(s)

Berichrom Heparin UF Calibrator

Berichrom Heparin UF Control 1

Berichrom Heparin UF Control 2

C Regulatory Information

1	CFR Section(s)	864 5425 - MULTIPURPOSE SYSTEM FOR IN VITRO COAGULATION STUDIES
2	Classification(s)	Class II
3	Classification Panel(s)	Hematology (81)
4	Product Code(s)	JPA, GIZ, GGC

D Predicate Device(s)

Dade Behring Heparin Calibrator and Controls – K042941

E Device Description(s)

Benchrom Heparin UF Calibrator

Benchrom Heparin UF Calibrator is a lyophilized product containing unfractionated (UF) heparin from porcine intestine and buffered human plasma Each package contains 6 vials, each vial requires reconstitution with 1 0 mL distilled or deionized water

Benchrom Heparin UF Control 1

Benchrom Heparin UF Control 1 is a lyophilized, low level, assayed control containing unfractionated (UF) heparin from porcine intestine and buffered human plasma Each package contains 6 vials, each vial requires reconstitution with 1 0 mL distilled or deionized water

Benchrom Heparin UF Control 2

Benchrom Heparin UF Control 2 is a lyophilized, high level, assayed control containing unfractionated (UF) heparin from porcine intestine and buffered human plasma Each package contains 6 vials, each vial requires reconstitution with 1 0 mL distilled or deionized water

F Device Intended Uses

Benchrom Heparin UF Calibrator

For the calibration of the Benchrom Heparin assay for measurement of unfractionated (UF) heparin

Benchrom Heparin UF Control 1

For use as a low level assayed control for the quantitative measurement of unfractionated (UF) heparin with the Benchrom Heparin assay

Benchrom Heparin UF Control 2

For use as a high level assayed control for the quantitative measurement of unfractionated (UF) heparin with the Benchrom Heparin assay

G Substantial Equivalence Information.

The Benchrom Heparin UF Calibrator, like the Dade Behring Heparin Calibrator, is intended for the calibration of the Benchrom Heparin assay for the measurement of unfractionated (UF) heparin Both the proposed device and the predicate device also share similarities in form, matrix and analyte measured

The Benchrom Heparin UF Control 1 and Benchrom Heparin UF Control 2 like, the Dade Behring Heparin Controls are assayed quality control materials and are intended for the measurement of UF heparin in the low and high concentration range, respectively Both the proposed devices and the predicate also share similarities in form, matrix and analyte measured

H Conclusion

Based on the information provided, the proposed devices are substantially equivalent to their respective predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics, Inc
c/o Ms Janet M Fose
Regulatory Affairs Specialist
500 GBC Drive, M/S 514
P O Box 6101
Newark, DE 19714

JAN 2 6 2009

Re k083175
Trade/Device Name Berichrom Heparin UF Calibrator
Berichrom Heparin UF Control 1
Berichrom Heparin UF Control 2
Regulation Number 21 CFR 864 5425
Regulation Name Multipurpose System for In Vitro Coagulation Studies
Regulatory Class Class II
Product Code JPA, GGC, GIZ
Dated October 27, 2008
Received October 28, 2008

Dear Ms Fose

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Parts 801 and 809), and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) This letter will allow you to begin

marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Maria M Chan

Maria M Chan, Ph D
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083175

Device Name:
Benchrom Heparin UF Calibrator

Indications for Use:
Benchrom Heparin UF Calibrator is an *in vitro* diagnostic product used for the calibration of the Benchrom Heparin assay for measurement of unfractionated (UF) heparin

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Office of In Vitro Diagnostic Device Evaluation and Safety

K083175

Indications for Use

510(k) Number (if known): K083175

Device Name:
Berichrom Heparin UF Control 1

Indications for Use
Berichrom Heparin UF Control 1 is an assayed, low level, quality control material for assessment of precision and analytical bias in the quantitative determination of unfractionated (UF) heparin with the Berichrom Heparin assay

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _______ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

In Vitro Diagnostic

K083175

Indications for Use

510(k) Number (if known): K083175

Device Name:
Berichrom Heparin UF Control 2

Indications for Use:
Berichrom Heparin UF Control 2 is an assayed, high level, quality control material for assessment of precision and analytical bias in the quantitative determination of unfractionated (UF) heparin with the Berichrom Heparin assay

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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